

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

Key Dates

Release date: September 24, 2014

Effective date: September 24, 2015

Relevant Notices

See the U.S. Government Science, Safety, Security (S3) website at: <http://www.phe.gov/s3/dualuse>.

Issued By

The United States Government

Overview

Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called “dual use research.” Dual use research *of concern* is a subset of dual use research defined as: “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.” *The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: <http://www.phe.gov/s3/dualuse>.

All provisions in this Policy supersede those contained in the previous draft policy published on February 22, 2013 (Federal Register 78 (36): 12369-12372). This Policy and the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, which was released on March 29, 2012 (<http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>) are complementary and emphasize a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

Contents

Section 1. Introduction.....	3
Section 2. Purpose	5
Section 3. Guiding Principles for Oversight of Life Sciences Dual Use Research	5
Section 4. Definitions	6
Section 5. Policy Statement	7
Section 6. Applicability of this Policy and Scope of Oversight of DURC.....	8
6.1. Applicability.....	8
6.2. Scope of Research Requiring Oversight	8
6.2.1. Agents and toxins.....	9
6.2.2. Categories of experiments	9
6.3. Compliance.....	9
Section 7. Organizational Framework for Oversight of DURC	10
7.1. Responsibilities of Principal Investigators.....	11
7.2. Responsibilities of USG-Funded Research Institutions	12
7.3. Responsibilities of USG Funding Agencies	17
7.4. Responsibilities of the USG	17
Section 8. Resources for Institutional Oversight of DURC	18

Section 1. Introduction

Life sciences research is essential to the scientific advances that underpin improvements in public health and safety, agriculture (including crops and other plants and animals) the environment, materiel¹, and national security. Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called “dual use research.” For the purposes of this Policy, dual use research *of concern* (DURC) is a subset of dual use research defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

In general, there are risks associated with life sciences research, such as accidental exposure of personnel or the environment to a pathogen or toxin. Many existing and complementary statutes, regulations, and guidelines are in place to address risks associated with biosafety, physical security, and personnel reliability.² Some risks relate directly to the characteristics of DURC – the risk that knowledge, information, products, or technologies resulting from the research could be used in a manner that results in harm or threatens society. DURC should be evaluated for possible risks, as well as benefits, in all these domains, to ensure that risks are appropriately managed and benefits realized. This Policy addresses dual use research risks holistically, that is, the risk that knowledge, information, products, or technologies generated from life sciences research could be used in a manner that results in harm.

Funders of life sciences research and the institutions and scientists who receive those funds have a shared responsibility for oversight of DURC and for promoting the responsible conduct and communication of such research. A comprehensive oversight system must include both the U.S. Government (USG) and institutional oversight processes. The goal of oversight is to preserve the benefits of life sciences research while minimizing the risk that knowledge, information, products, or technologies generated by such research could be used in a manner that results in harm. On March 29, 2012, the USG issued its “Policy for Oversight of Life Sciences Dual Use Research of Concern” (*March 2012 DURC Policy*).³ That policy formalized a process of regular USG review of USG-funded or -conducted research with certain high-consequence pathogens and toxins to identify DURC and implement risk mitigation measures, where applicable.

¹ Materiel includes food, water, equipment, supplies, or material of any kind.

² E.g., the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331); *NIH Guidelines on Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines, <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>); *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 5th Edition (<http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>).

³ *The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*, March 29, 2012, <http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>.

This Policy, the “United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,” addresses institutional oversight of DURC. Oversight includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. Institutional oversight of DURC is a critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC. This Policy and the *March 2012 DURC Policy* are complementary and emphasize a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.⁴

The components outlined in the *March 2012 DURC Policy* and in this Policy will be updated, as needed, following domestic dialogue, international engagement, and input from interested communities including scientists, national security officials, global health specialists, and the general public.

The USG has limited the scope of this Policy (Section 6.2) as well as the *March 2012 DURC Policy* to a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments. The USG will solicit feedback on the experience of institutions in implementing the Policy; will evaluate the impact of DURC oversight on the life sciences research enterprise; will assess the advantages and disadvantages of expanding the scope of the Policy to encompass additional agents and toxins and/or categories of experiments; and will update the Policy, as warranted. Research institutions are encouraged to be mindful that research outside of the scope articulated in this Policy (Section 6.2) may also constitute DURC. Institutions have the discretion to consider other categories of research for DURC potential and may expand their internal oversight to other types of life sciences research as they deem appropriate, but such expansion would not be subject to oversight as articulated in this Policy.

It is important to note that life sciences research that meets the definition of DURC often increases our understanding of the biology of pathogens; makes critical contributions to the development of new diagnostic, prevention, and treatment measures; improves public, animal, and plant health surveillance; and enhances emergency preparedness and response efforts. Thus, designating research as DURC should not be seen as a negative categorization, but simply an indication that the research may warrant additional oversight in order to reduce the risks that the knowledge, information, products, or technologies generated could be used in a manner that results in harm. As a general matter, designation of research as DURC does not mean that the research should not be conducted or communicated.

Nothing in this Policy should be read as superseding U.S. Department of Health and Human Services or Department of Agriculture statutory authority to regulate the possession, use, or

⁴ The *March 2012 DURC Policy* and this Policy are complemented by extant laws and treaties (e.g. Title 18, U.S. Code, Section 175 and the Biological and Toxin Weapons Convention) that prohibit the development, production, acquisition, or stockpiling of biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes and that prohibit the use of biological agents and toxins as weapons.

transfer of biological agents and toxins that have the potential to pose a severe risk to public health and safety, animal and plant health or animal and plant products; or provisions of the select agent regulations found at 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331; nor the export control regulations at 15 CFR Parts 730-774 (known as the “Export Administration Regulations”[EAR]), and 22 CFR Parts 120-130 (known as the “International Traffic in Arms Regulations”[ITAR]). Note that the term “dual use” should not be interpreted to indicate which regulations govern the export of these items, and that some of the DURC agents/experiments are controlled by the ITAR and not the EAR.

This Policy will take effect on September 24, 2015, which is 12 months after its release date. A 12-month time frame will allow institutions and USG funding agencies subject to this Policy to establish the procedures necessary to comply with this Policy. Institutions to which this Policy applies, as defined in Section 6.1 are required to certify at the time of seeking funding (e.g., by signing the face page of a grant application), but no sooner than the effective date of this Policy, that they are in compliance with all aspects of this Policy.

Section 2. Purpose

The purpose of this Policy is to strengthen ongoing institutional review and oversight of certain life sciences research with high-consequence pathogens and toxins in order to identify potential DURC and mitigate risks where appropriate. This Policy delineates the roles and responsibilities of USG funding agencies, research institutions, and life scientists, and provides requirements and performance standards for review of life sciences research, identification of potential DURC, and development and implementation of risk mitigation measures for DURC, where applicable. In so doing, the Policy seeks to preserve the benefits of life sciences DURC while minimizing the risk that the knowledge, information, products, or technologies generated from such research could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Section 3. Guiding Principles for Oversight of Life Sciences Dual Use Research

The following principles serve as a guide for oversight of life sciences dual use research generally:

- A. Life sciences research underpins advances in public health, agriculture, the environment, and other pertinent areas, and significantly strengthens national security and the economy.
- B. Life sciences research has the potential to produce beneficial knowledge, information, technology, or products that can also be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, or the environment. Therefore, it is appropriate to have in place a framework and tools for the responsible oversight, conduct, and communication of such research.
- C. Life sciences research is by nature dynamic and can produce unanticipated results and must be evaluated on an ongoing basis for dual use potential.

- D. Oversight of DURC must recognize both the need for security and the need for research progress; as such, the degree of oversight should be commensurate with the possible consequences of misuse.
- E. Effective oversight helps maintain public trust in the life sciences research enterprise by demonstrating that the scientific community recognizes the implications of DURC and is acting responsibly to protect public welfare and preserve security.
- F. USG agencies that fund DURC, the recipients of those public funds, and individuals who conduct this research share the oversight responsibility.
- G. It is essential to have a consistent approach to the oversight of DURC.
- H. Any oversight process for DURC should be periodically evaluated both for effectiveness and impact on the research enterprise.
- I. The free and open conduct and communication of life sciences research is vital to a robust scientific enterprise and will continue to be the goal of the USG. It also should continue to be the goal of institutions engaged in life sciences research.
- J. Educating the scientific community about the dual use potential of life sciences research and cultivating a sense of responsibility for dual use research among life scientists is essential for promoting responsible research behavior.
- K. No policy or set of guidelines can anticipate every possible situation. Motivation, awareness of the dual use issue, and good judgment are key considerations in the responsible evaluation of research for dual use potential. It is incumbent on those engaged in life sciences research to adhere to the intent of this Policy as well as to the performance standards described herein.

Section 4. Definitions

For the purpose of this Policy the following terms are defined:

- A. “To certify” is to attest to the USG that an institution subject to this Policy will comply with all aspects of this Policy.
- B. “Dual use research” is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.
- C. “Dual use research of concern” (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat

with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

- D. “Institution” is any government agency (Federal, State, tribal, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity conducting research.
- E. “Institutional Contact for Dual Use Research” (ICDUR) is an individual designated by the institution to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant USG funding agency.
- F. “Institutional Review Entity” (IRE) is a committee established by the institution as described in Section 7.2.E and empowered to execute the requirements in Section 7.2.B.i- iii, v, and viii.
- G. “Life sciences” pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.
- H. “National Science Advisory Board for Biosecurity” (NSABB) is a USG advisory committee established to advise the USG on dual use research issues as requested.
- I. “Principal Investigator” (PI) is an individual who is designated by the research institution to direct a project or program and who is responsible to the funding agency or the research institution for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project within a single or multiple institutions.

Section 5. Policy Statement

It is the policy of the USG that:

- A. Life sciences research that meets the scope specified in Section 6.2 of this Policy is subject to USG (through the *March 2012 DURC Policy*) as well as institutional oversight (as described in this Policy). The purpose of this oversight is to preserve the benefits of such research while minimizing the risk that the knowledge, information, products, or technologies generated by DURC could be used in a manner that results in harm to

public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security; and

- B. Oversight includes the identification of life sciences research that raises dual use concerns as well as the implementation of measures to mitigate the risk that DURC is used in a manner that results in harm. Measures that mitigate the risks of DURC should be applied in a manner that minimizes, to the extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.

Section 6. Applicability of this Policy and Scope of Research Requiring Oversight

6.1. Applicability

This Policy applies to:

- A. USG departments and agencies that fund or conduct life sciences research.
- B. Institutions within the United States that both:
 - i. Receive USG funds to conduct or sponsor life sciences research; and
 - ii. Conduct or sponsor research that involves one or more of the 15 agents or toxins listed in Section 6.2.1, even if the research is not supported by USG funds.
- C. Institutions outside of the United States that receive USG funds to conduct or sponsor research that involves one or more of the 15 agents or toxins listed in Section 6.2.1.

Institutions that do not receive USG funds for life sciences research, but conduct life sciences research that has the potential to generate knowledge, information, products, or technologies that could be used in a manner that results in harm, are not subject to oversight as articulated in this Policy; however, they are strongly encouraged to implement internal oversight procedures consistent with the culture of shared responsibility underpinning this Policy.

6.2. Scope of Research Requiring Oversight

Consistent with the *March 2012 DURC Policy*, under this Policy, research that uses one or more of the agents or toxins listed in Section 6.2.1, and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed in Section 6.2.2 will be evaluated for DURC potential.

6.2.1. Agents and toxins⁵

- a) Avian influenza virus (highly pathogenic)
- b) *Bacillus anthracis*
- c) Botulinum neurotoxin⁶
- d) *Burkholderia mallei*
- e) *Burkholderia pseudomallei*
- f) Ebola virus
- g) Foot-and-mouth disease virus
- h) *Francisella tularensis*
- i) Marburg virus
- j) Reconstructed 1918 Influenza virus
- k) Rinderpest virus
- l) Toxin-producing strains of *Clostridium botulinum*
- m) Variola major virus
- n) Variola minor virus
- o) *Yersinia pestis*

6.2.2. Categories of experiments

- a) Enhances the harmful consequences of the agent or toxin
- b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- c) Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- e) Alters the host range or tropism of the agent or toxin
- f) Enhances the susceptibility of a host population to the agent or toxin
- g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in 6.2.1, above

6.3. Compliance

Non-compliance with this Policy may result in suspension, limitation, or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded

⁵ The 15 agents and toxins listed in this Policy are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. It is important to note, however, that the Federal Select Agent Program does not oversee the implementation of this Policy or the *March 2012 DURC Policy*.

⁶ For the purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.

research, and may subject the institution to other potential penalties under applicable laws and regulations. While each USG funding agency is responsible, in accordance with its relevant statutory and regulatory authorities, for determining how best to ensure compliance with the oversight requirements set forth in this Policy for research it funds, the USG will develop and promulgate consistent processes for this purpose.

Section 7. Organizational Framework for Oversight of DURC

This Section describes the organizational framework for review of research with dual use potential and the oversight of DURC and articulates the roles and responsibilities of PIs, institutions, USG funding agencies, and the USG under this Policy. Components of the review and oversight system for DURC include:

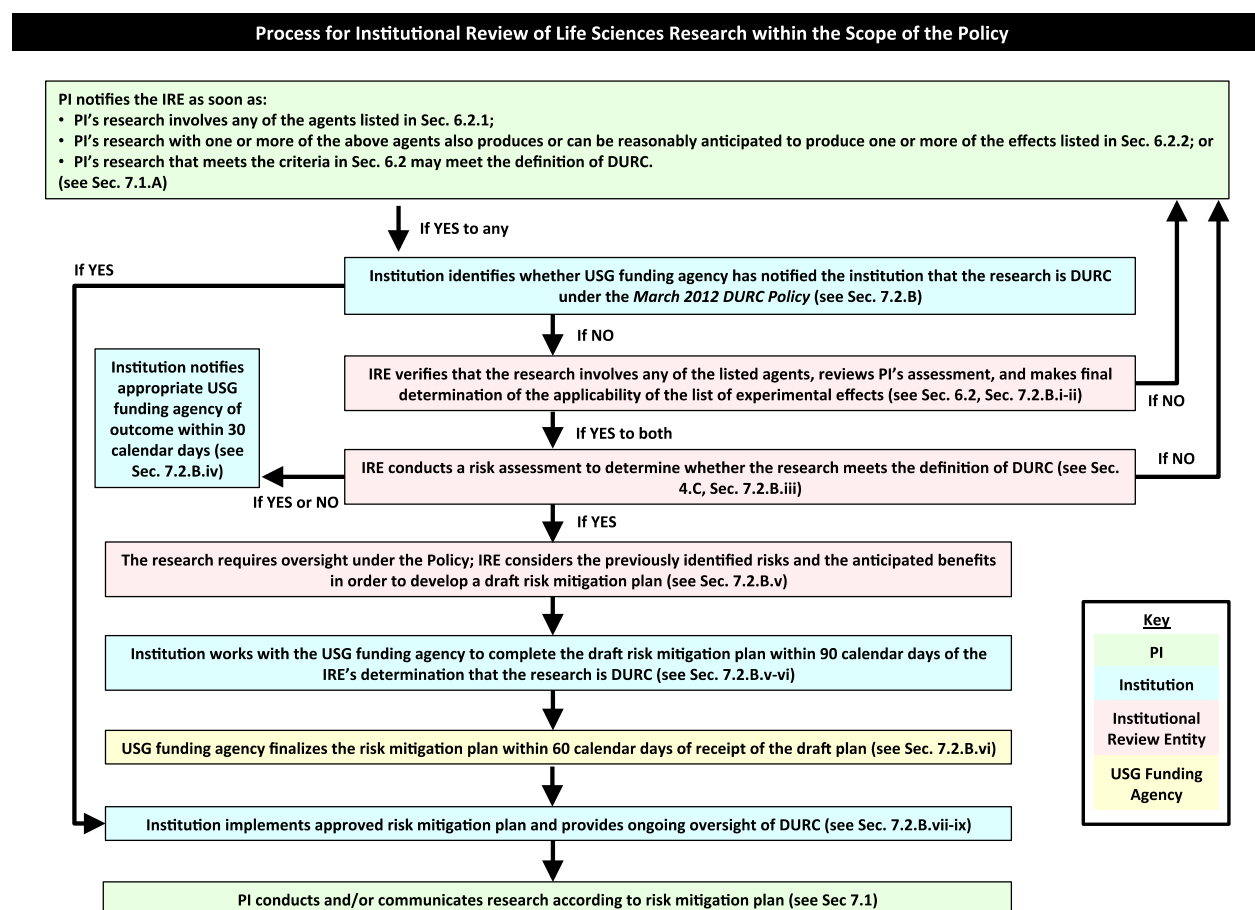
- A. Identification, by the PI, of life sciences research that involves one or more of the 15 agents or toxins listed in Section 6.2.1.
- B. An institutional review process for assessing whether research that uses one or more of the agents or toxins listed in Section 6.2.1 also produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2.
- C. For research anticipated to produce at least one of the seven effects, determination of whether the research meets the definition of DURC in Section 4.C. A risk assessment should underpin the determination of DURC (see Section 8.A for resources for this assessment).
- D. Identification of the anticipated benefits of the research identified as DURC (see Section 8.A for resources for this assessment). The anticipated benefits should be considered in conjunction with the previously identified risks (see Section 7.C) in order to develop a draft risk mitigation plan to guide the conduct and communication of the DURC. The risk mitigation plan must be approved by the USG funding agency. Plans should be evaluated by the institution at least annually and modified as necessary for the duration of the research. Institutions are responsible for ensuring that the DURC is conducted in accordance with the risk mitigation plan. Research that has already been determined to be DURC under the *March 2012 DURC Policy*, and for which a risk mitigation plan has already been developed, does not need a new risk mitigation plan but the extant risk mitigation plan will be subject to ongoing review and modification, as necessary, by the institution.
- E. Notification of the results of this review process to the relevant USG funding agency and, in instances when the research is determined to be DURC, provision of the draft risk mitigation plan by the institution to the USG funding agency. For non-USG funded research, notification should be made to the National Institutes of Health (NIH)⁷ which

⁷ For non-USG funded research, notifications of the results of the review process should be submitted to the NIH Program on Biosecurity and Biosafety Policy at DURC@od.nih.gov.

will receive the notification for administrative purposes and will in turn refer the notification to an appropriate agency based upon the nature of the research.

- F. For institutions subject to this Policy, certify that the institution will comply with this Policy.
- G. Oversight by USG funding agencies and the USG as articulated in the *March 2012 DURC Policy* with additional responsibilities with respect to this Policy described in Sections 7.3 and 7.4 below.

Figure 1 provides an overview of the process for institutional review of life sciences research within the scope of the Policy.



7.1. Responsibilities of Principal Investigators

In accordance with this Policy, PIs are to:

- A. Notify the Institutional Review Entity (IRE) as soon as:
 - i. The PI's research involves one or more of the agents or toxins listed in Section 6.2.1;

- ii. The PI's research with one or more of the agents or toxins listed in Section 6.2.1 also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven effects listed in Section 6.2.2; or
- iii. The PI's research that is within the scope of Section 6.2 may meet the definition of DURC.

The notification must include the PI's assessment of whether any research involving these agents or toxins produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2.

- B. Work with the IRE to assess the dual use risks and benefits of the DURC and to develop risk mitigation measures.
- C. Conduct DURC in accordance with the provisions in the risk mitigation plan.
- D. Be knowledgeable about and comply with all institutional and USG policies and requirements for oversight of DURC.
- E. Ensure that laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting life sciences research with one or more of the agents listed in Section 6.2.1 of this Policy have received education and training on DURC.
- F. Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the approved risk mitigation plan (per Section 7.2.B.vii)

7.2. Responsibilities of USG-Funded Research Institutions

In accordance with this Policy, research institutions (Federal and non-Federal) that receive USG funds for life sciences research and conduct or sponsor research with any of the 15 agents or toxins listed in Section 6.2.1 are to:

- A. Establish and implement internal policies and practices that provide for the identification and effective oversight of DURC.
- B. When research is identified by a PI (per Section 7.1.A) as utilizing one of the agents or toxins listed in Section 6.2.1, initiate an institutional review and oversight process (Figure 1) that includes the steps below (Section 7.2.B.i-ix), as applicable. Research that has already been determined to be DURC under the *March 2012 DURC Policy*, and for which a risk mitigation plan has already been developed, is not required to

undergo steps 7.2.B.i-vi, but will be subject to ongoing review and notification per Section 7.2.B.viii-ix.

- i. Verification, by an IRE, that the research identified by the PI utilizes one or more of the agents or toxins listed in Section 6.2.1.
- ii. Review, by an IRE, of the PI's assessment of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2 and final determination of their applicability. If the IRE determines that the research in question does not involve one or more of the categories of experiments detailed in Section 6.2.2, the research is not subject to additional review or oversight (i.e., the steps detailed in 7.2.B.iii-ix, below), but shall continue to be assessed by the PI per Section 7.1.A.
- iii. If the research has been assessed per Section 7.2.B.ii to meet the scope of the Policy (Sections 6.2.1 and 6.2.2), determination, by an IRE, of whether the research meets the DURC definition (Section 4.C). Note that a risk assessment (see Section 8.A for resources for this assessment) should underpin both the determination of DURC and the subsequent development of a draft risk mitigation plan (step 7.2.B.v, below). The PI should be included in these activities, as appropriate. If the IRE determines that the research in question does not meet the definition of DURC, the research is not subject to additional DURC oversight (i.e., the steps detailed in 7.2.B.v-ix, below), but the institution shall notify the appropriate USG funding agency of the institutional review findings (step 7.2.B.iv, below). If the IRE determines that the research in question meets the definition of DURC, all additional review and DURC oversight steps shall be followed. Research that has been determined to be DURC should not be conducted until an approved risk mitigation plan is in place.
- iv. Within 30 calendar days of the institutional review of the research for DURC potential, notification to the USG funding agency of any research that involves one or more of the 15 listed agents and one or more of the seven listed experimental effects (Section 6.2), including whether it meets or does not meet the definition of DURC. For non-USG funded research, notification should be made to NIH,⁸ which will in turn refer the notification to an appropriate USG funding agency, based upon the nature of the research (per Section 7.E). This initial notification should include: the grant or contract number related to the research (if the research is funded by the USG); the name(s) of PI(s); the name(s) of the agent(s) listed in Section 6.2.1 of the Policy; and a description of why the research is deemed to produce one or more of the experimental effects listed in Section 6.2.2 of the Policy. For research that is determined by the IRE to meet the definition of DURC, the notification should also include: the name of the investigator (if different from

⁸ For non-USG funded research, notifications of the results of the review process should be submitted to the NIH Program on Biosecurity and Biosafety Policy at DURC@od.nih.gov.

- the PI) responsible for the performance of the DURC; and a description of the IRE's basis for its determination.
- v. Identification by the IRE of the anticipated benefits of the research identified as DURC (see Section 8.A for resources for this assessment). The anticipated benefits should be considered in conjunction with the previously identified risks (see Section 7.2.B.iii) in order to develop a draft risk mitigation plan to guide the conduct and communication of the DURC. Institutions should work with both the PI and USG funding agency, or for non-Federally funded DURC, the NIH-designated USG agency (per Section 7.E) to develop a risk mitigation plan. Research that has already been determined to be DURC under the *March 2012 DURC Policy*, and for which a risk mitigation plan has already been developed, does not need a new risk mitigation plan but the extant risk mitigation plan will be subject to ongoing review and modification, as necessary, by the IRE (per Section 7.2.B.viii).
 - vi. Within 90 calendar days of an IRE's determination that the research is DURC, provision of the draft risk mitigation plan (developed per Section 7.2.B.v) to the USG funding agency for final review and approval. In the case of non-USG funded research, draft risk mitigation plans should be provided to the USG agency designated by NIH (per Section 7.E). Per Section 7.3.D, USG agencies must provide an initial response within 30 calendar days and should finalize the plan within 60 calendar days of receipt of the draft plan.
 - vii. Implementation of the risk mitigation plan. After a risk mitigation plan is developed (per this Policy or the *March 2012 DURC Policy*) and is approved by the USG funding agency, the DURC must be conducted in accordance with that plan.
 - viii. IRE review, at least annually, of all active risk mitigation plans. If the research in question still constitutes DURC, the IRE should modify the plan as needed.
 - ix. Notification, within 30 calendar days, of: 1) any change in the status of a DURC project at the institution (including whether the research is determined by the IRE to no longer meet the definition of DURC), and 2) details of any changes to risk mitigation plans (such changes need to be approved by the funding agency). Such notification should be made to the USG funding agency or, in the case of non-USG funded research, to the USG agency designated by NIH (per Section 7.E).
- C. Ensure that internal policies establish a mechanism for the PI to immediately refer a project to the IRE as soon as:
- i. The PI's research involves one or more of the agents or toxins listed in Section 6.2.1;
 - ii. The PI's research with one or more of the agents or toxins listed in Section 6.2.1 also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven effects listed in Section 6.2.2; or
 - iii. The PI's research that falls within the scope of Section 6.2 may meet the definition of DURC.

- D. Designate an Institutional Contact for Dual Use Research (ICDUR) to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of Section 6.2 and/or meets the definition of DURC. If questions arise regarding compliance, implementation of this Policy, or the *March 2012 DURC Policy*, or when guidance is needed about identifying DURC or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the institution and the relevant program officers at the USG funding agencies, or for non-USG funded research, between the institution and NIH (or the USG agency to which NIH refers the institution).
- E. Establish an IRE to execute the requirements in Section 7.2.B.i-iii, v, and viii, above. A range of mechanisms for fulfilling the role of an IRE are acceptable as long as the review entity is appropriately constituted and authorized by the institution to conduct the dual use review. Options include: (1) a committee established for dual use review; (2) an extant committee (such as an Institutional Biosafety Committee [IBC]) whose constitution meets or could meet, with the addition of new or ad hoc members, the requirements and attributes outlined below; or (3) an externally administered committee (e.g., an IBC or review entity at a neighboring or regional institution or a commercial entity).

Regardless of the mechanism selected to fulfill the institutional responsibility of reviewing research that falls within the scope of Section 6.2.1, the IRE must be composed of at least five members and:

- i. Be sufficiently empowered by the institution to ensure it can execute the requirements of Section 7.2.B.i-iii, v, and viii;
 - ii. Include persons with sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at a given research facility;
 - iii. Include persons with knowledge of relevant USG policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity. The review entity may also include, or have available as consultants, at least one person knowledgeable in the institution's commitments, policies, and standard operating procedures;
 - iv. On a case by case basis, recuse any member of an IRE who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the review entity; and
 - v. Engage in an ongoing dialogue with the PI of the research in question when conducting a risk assessment and developing a risk mitigation plan.
- F. Maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

- G. Provide education and training on DURC for individuals conducting life sciences research with one or more of the agents listed in Section 6.2.1 of this Policy, and maintain records of such education and training for the term of the research grant or contract plus three years after its completion. Institutions may also wish to address dual use topics in existing courses on research ethics or the responsible conduct of research. Institutions may require additional record keeping and should designate an individual responsible for maintaining documentation.
- H. Ensure compliance with this Policy and with approved risk mitigation plans. Report instances of noncompliance with this Policy, as well as mitigation measures undertaken by the institution to prevent recurrences of similar noncompliance, within 30 calendar days to the USG funding agency. In the case of non-USG funded research, reports should be made to the USG agency designated by NIH (per Section 7.E of this Policy).
- I. As necessary, assist the PIs conducting life sciences research when questions arise about whether their research may require further review or oversight.
- J. Establish an internal mechanism for PIs to appeal institutional decisions regarding research that is determined by the IRE to meet the definition of DURC.
- K. Make information about the process for review of research subject to the Policy available upon request, as consistent with applicable law.
- L. When applying for or accepting USG funds for life sciences research, as applicable, certify that the institution will be or is in compliance with all aspects of this Policy.

Notes: There may be cases in which a Federal department or agency simply passes through funding from another Federal department or agency to support life sciences research at an institution that conducts or sponsors research involving any of the agents listed in Section 6.2.1. In this instance, the agency originally providing the funding shall be considered the USG funding agency, and the ultimate recipient of the funds shall be considered the institution, and respectively shall fulfill the requirements expected of each under this Policy.

The USG also recognizes that there will be situations where elements of a potential DURC project are being carried out at multiple institutions through a subaward with a primary institution which directly receives the grant or contract from the USG funding agency. In cases of such collaborations involving multiple institutions via a subaward, the primary institution is responsible for notifying the funding agency of research that falls within the scope of Section 6.2 and, if that research is determined to be DURC, providing copies of each institution's risk mitigation plan. Furthermore, the primary institution should ensure that DURC oversight is consistently applied by all entities participating in the collaboration.

7.3. Responsibilities of USG Funding Agencies

The oversight process and the roles and responsibilities of the USG departments and agencies that fund life sciences research are delineated in the complementary *March 2012 DURC Policy*. In conjunction with the requirements delineated in the *March 2012 DURC Policy*, USG funding agencies are to:

- A. Require all institutions they fund that meet the applicability criteria in Section 6.1 to implement this Policy.
- B. Respond to questions from institutions regarding the oversight of DURC and provide guidance to institutions regarding compliance with this Policy.
- C. For USG agency-funded and proposed life sciences research that meets the criteria listed in Section 6.2.1, assess the applicability of the criteria listed in Section 6.2.2, and for such research that also meets the definition of DURC, complete a risk assessment prior to the funding decision and when progress reports are submitted by PIs. USG funding agencies will review projects on an ongoing basis for DURC and are to:
 - i. For research that meets the criteria in Section 6.2.1, notify an institution when the USG funding agency determines that the research meets the criteria listed in Section 6.2.2 and meets the definition of DURC;
 - ii. Notify an institution when the USG funding agency does not agree with an institution's assessment of the applicability of the criteria listed in Section 6.2.2 or with an institution's determination of the DURC status of such research;
 - iii. Review institutional risk mitigation plans (and any subsequent changes) and notify an institution of concerns or disagreements with a risk mitigation plan;
 - iv. Prior to reaching its final determination, consult with institutions to address disagreements identified in accordance with 7.3.C.i, ii, and iii above.
- D. Provide an initial response to the institution within 30 calendar days from receipt of material or inquiry. In cases of DURC, finalize risk mitigation plans in a timely fashion, but no later than 60 calendar days after initial submission of the draft plan by the institution.
- E. Respond to reports of non-compliance with this Policy and work with institutions to address such non-compliance.
- F. For research institutions in low-resource environments outside of the United States that receive USG funds, consider serving as the implementing IRE if appropriate.

7.4. Responsibilities of the USG

In accordance with this Policy, the USG is to:

- A. Develop training tools and materials for use by the USG agencies and by institutions implementing this Policy.
- B. Provide education and outreach to stakeholders about dual use policies and issues.
- C. Provide guidance to institutions on the sharing of DURC research products and on the communication of DURC.
- D. Convene advisory bodies such as NSABB, as necessary, to develop recommendations on particularly complex cases of DURC.
- E. Periodically assess the impact of this Policy on life sciences research programs and institutions, and update this Policy and the *March 2012 DURC Policy*, as appropriate. This should be informed by national and international dialogue with interested communities, including scientists, research administrators, security experts, and public health officials.

Section 8. Resources for Institutional Oversight of DURC

It is the expectation of the USG that PIs and institutions will be able to identify, assess, and appropriately manage DURC. To assist in these processes, the following resources are available for optional use:

- A. Guidance documents for DURC oversight. The USG has developed a compendium of tools to assist investigators and research institutions in the implementation of DURC oversight outlined in this Policy and the *March 2012 DURC Policy*⁹. These tools will aid in the understanding and identification of DURC, the risk assessment and development of risk mitigation plans and risk management processes, the responsible communication of DURC, and training and education on DURC.
- B. Consultation with the USG funding agency. Institutions may consult with the USG department or agency that is funding the research in question for advice on matters related to DURC. Such consultations should involve the ICDUR. The funding agency program officers can provide guidance on DURC issues. Questions regarding non-USG funded research should be directed to NIH or to the USG funding agency to which NIH refers the institution based on the nature of the research in question. Consultation with the funding agency is not mandatory or intended as a substitute for institutional dual use review or the reporting requirements (see Section 7.2.B above). Such consultations may be appropriate when:

⁹ These tools can be accessed at the U.S. Government Science, Safety, Security (S3) website at <http://www.phe.gov/s3/dualuse>.

- i. The IRE requires guidance on developing an adequate risk mitigation plan in cases where the potential risks are perceived as particularly high;
- ii. The IRE considers the only viable risk mitigation measure to be not conducting or not communicating the research in question;
- iii. The PI does not agree with the finding of the IRE and so the institution would like to request outside advice;
- iv. The research in question represents a particularly complex case or appears to fall outside the scope of this Policy, but still seems to present significant concerns; or
- v. Guidance is required to ensure a clear understanding of how the USG interprets the definition of DURC and related terms.